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| 10/559,950   | 11/08/2006  | Roger William Frank Ashton | 10557/323978        | 1482             |
| 30559 7590 07/17/2008<br>CHIEF PATENT COUNSEL<br>SMITH & NEPHEW, INC.<br>1450 BROOKS ROAD<br>MEMPHIS, TN 38116 |             |                            |                     |                  |
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| SWEET, THOMAS  |             |                            |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/559,950

**Applicant(s)**

ASHTON ET AL.

**Examiner**

Thomas J. Sweet

**Art Unit**

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-14, 16-26 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-14, 16-26 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Response to Arguments***

**DETAILED ACTION**

***Response to Arguments***

Applicant's arguments, see page 8, filed 02/04/2008, with respect to the specification have been fully considered and are persuasive. The objection of specification has been withdrawn. Even though, the amendment was not in the proper form of a replacement sheet. The Examiner will amended at allowance to correct the subheading as requested.

Applicant's arguments filed 02/04/2008 have been fully considered but they are not persuasive. Although Hauser has a preferred configuration with the set screw in recess 16, it is fully capable of being adjusted such that 11 is off set from 3 and the dovetail and set screw still function as a connection. The screw of Hauser is also fully capable of securing a second component such as a washer, spacer/spacer or even bone ingrowth between the members. The claim include both of these limitations as intended use for which a reference only needs to be fully capable of the use and does not need to positively claim the structure involved. Regarding the rejection of claims 8-12 and 16, White does include a male feature since if fits in a female recess and include slits for biasing the teaching is applicable to the male feature of Hauser. Regarding the rejection of claim 13, claim 13 mere required a teaching a resilient material for which prima fascia rational is properly applied. Regarding the rejection of claim 18, Gustilo does include a circumferential groove which as used in the modification meets claim 18.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-14, 16-22, 26 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a second component, does not reasonably provide enablement for a first component. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The second component is solely discloses as a patient's bone which is not a component since it is non-statutory subject matter which can not be considered as a component of the invention. The claims are being treated as intended use so there is no 35 USC 101 issue

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 14, 17, 19-22 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (U.S. Patent No. 5,549,692).

Regarding Claims 1-7, 19, and 22: Hauser et al. teaches a fixing assembly comprising: a component 3 having a surface with a male location feature that has portions that are flat and/or conical in profile, a fixing member 11 having a female location feature 17 and apertures 9 and 16, and fixing screws 8 and 13 that go through the apertures (FIG. 1, 2a-c, and 6). One of the fixing screws 8 is external to the surface of the component (FIG. 1) and secures the component to

a second component. The male and female features have corresponding undercuts (FIG. 1) that form a dovetail joint to secure the fixing member to the surface of the component; and wherein the orientation of the fixing member relative to the surface of the component is adjustable wherein the fixing screw is available for securing the component to a second component; and wherein the orientation of the fixing member relative to the surface of the component is fully capable being adjustable (“available” and “orientation” are both intended use recitations for which the device of Hauser et al is fully capable of the use since the fixing screw could be used in secure for example a wash/shim in between 3 and 11 as well as anchoring ingrowth of bone/tissue and adjusting such that 11 is off set from 3 and the dovetail and set screw still function as a connection).

Regarding Claims 14: Hauser et al. teaches that the surface location feature is at least partly located on a rim of the surface (FIG. 1).

Regarding Claims 17: Hauser et al. teaches that the surface of the component has a threaded portion 12 adjacent a location feature.

Regarding Claims 20 and 21: Hauser et al. teaches that the component is a prosthetic ball and socket joint cup, specifically an acetabular cup (abstract).

Regarding Claim 28: Hauser et al. teaches that the fixing screw 8 has a head (FIG. 1).

Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hauser et al. (U.S. Patent No. 5,549,692),

Regarding Claims 23, 24 and 26: Hauser et al. teaches a kit of parts for a fixing assembly comprising; at least one component 3 having a surface with a male location feature that has

portions that are flat and/or conical in profile, a fixing member 11 that is secured to the external surface of the component and has a female location feature 17 and apertures 9 and 16, and fixing screws 8 and 13 that go through the apertures (FIG. 1, 2a-c, and 6) and secure the component to a second component. One of the fixing screws 8 is external to the surface of the component (FIG. 1) and wherein the orientation of the fixing member relative to the surface of the component is fully capable being adjustable ("orientation" is intended an use recitations for which the device of Hauser et al is fully capable of the use since adjusting such that 11 is off set from 3 and the dovetail and set screw still function as a connection)..

Regarding Claim 25: Hauser et al. teaches that the component is a prosthetic ball and socket joint cup, specifically an acetabular cup (abstract).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Hauser et al. (U.S. Patent No. 5,549,692) as applied to claim 1 above and further in view of Pappas (U.S. Patent No. 6,475,241).

Hauser et al. teaches the basic fixing assembly as applied above.

Regarding Claim 8 and 9: Hauser et al. does not teach that the male feature has a slit. However, White et al. teaches a fixing member with a male feature that has slots 241/notches

243/slits (10:20-30 and FIG. 13a-b). Hauser et al. and White et al. are combinable because they are from the same field of endeavor, namely, hip prostheses.

At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the male feature taught by Hauser et al. with the slits taught by White et al., and one would have been motivated to do so in order to provide a mechanism for tightening the spike (10:25-30 and 10:50-61 ).

Regarding Claims 10 and 12 Hauser et al. also does not teach that the slit extends radially from the aperture. However, White et al. teaches a notch/slit 243 that extends radially from the aperture in a plane that is perpendicular to the axis of the aperture (FIG. 13b). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the male feature taught by Hauser et al. with the radial slits taught by White et al., and one would have been motivated to do so to provide a mechanism for tightening the spike (10:25-30 and 10:50-61 ).

Regarding Claim 11: Hauser et al. does not teach a slit that is formed in a plane that is substantially parallel to axis of aperture. However, White et al. teaches a slot/slit 241 that is formed in a plane that is substantially parallel to axis of aperture. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the male feature taught by Hauser et al. with the longitudinal slits taught by White et al., and one would have been motivated to do so to provide a mechanism for tightening the spike (10:25-30 and 10:50-61).

Regarding Claim 16: Hauser et al. teaches that the fixing screw 8 has a thickened portion.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (U.S. Patent No. 5,549,692) as applied to claim 1 and 7 above and further in view of Pappas (U.S. Patent No. 6,475,241).

Hauser et al. teaches the basic fixing assembly as applied above. Hauser et al. does not teach that the male feature is made of a resiliently deformable material. However, Pappas et al. teaches a male feature 430 which is made of plastic/a resiliently deformable material (6:25-31). Hauser et al. and Pappas et al. are combinable because they are from the same field of endeavor, namely, joint prostheses. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the male feature taught by Hauser et al. with the deformable material taught by Pappas et al., and one would have been motivated to do because a plastic/metal interface is less likely to slide and create debris which would cause inflammation than certain other types of interfaces.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauser et al. (U.S. Patent No. 5,549,692) as applied to claim 1 above and further in view of Gustilo et al. (U.S. Patent No. 6,162,257).

Hauser et al. teaches the basic fixing assembly as applied above.

Hauser et al. does not teach that the component has a circumferential groove. However, Gustilo et al. teaches a similar device with a circumferential groove (FIG. 8). Hauser et al. and Gustilo et al. are combinable because they are from the same field of endeavor, namely, hip prostheses. At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the surface of the component taught by Hauser et al. with the circumferential groove taught by Gustilo et al., and one would have been motivated to do so in



order to provide a mechanism for securing the inner layer of the acetabular cup 160 to the outerlayer (FIG. 7).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Paul, Kamaljit S. (US 20050216011).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:45am - 5:15pm, Tu-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas J Sweet/  
Primary Examiner, Art Unit 3774